K091607

5.3 510(k) Summary – Gamma-bsm

NOV – 2 2009

Submitter: ETEX Corporation
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Date Prepared: August 3, 2009

Product Code(s): MQV (21 CFR 888.3045)

Device Class: II (21 CFR 888.3045)

Classification Panel: Orthopaedics

FDA Panel Number: 87

Classification Name: Filler, Bone Void, Calcium Compound (21 CFR 888.3045)

Proprietary Name: Gamma-bsm Moldable Bone Substitute Material

Predicate Device(s): Gamma-bsm Moldable Bone Substitute Material (ETEX Corporation, K090242)
Vitoss Bioactive Foam Bone Graft Substitute (Orthovita, K083033)

Device Description: Gamma-bsm Moldable Bone Substitute Material is a synthetic, biocompatible bone graft substitute material. At the time of use, the powder component is combined with a specified volume of mixing solution and mixed to form a putty. The resulting putty is administered to the treatment site by manual application. The material can be shaped into a desired form *in-situ* prior to implantation. After the putty is applied to the treatment site, it hardens at body temperature and converts to an apatitic calcium phosphate material. The end product, poorly crystalline hydroxyl-apatite (PCHA), is of low crystalline order with a similar chemical and crystalline structure to that of natural bone

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minerals. Gamma-bsm Moldable Bone Substitute Material is an osteoconductive material that is resorbed and replaced by natural bone over time.

Intended Use: Gamma-bsm Moldable Bone Substitute Material is an implantable bone graft that is a synthetic calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (i.e. the extremities, posterolateral spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Gamma-bsm Moldable Bone Substitute Material is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Materials: Synthetic calcium phosphate

Performance Data: Regression testing consistent with *Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA Staff* (dated June 2, 2003) has been submitted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

ETEX Corporation
% Mr. Christopher Klaczyk
Regulatory Affairs Manager
38 Sidney Street, 3flr, The Clark Building
Cambridge, MA 02139

NOV - 2 2009

Re: K091607
Trade/Device Name: Gamma-bsm Moldable Bone Substitute Material
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone voice filler device
Regulatory Class: II
Product Code: MQV
Dated: September 11, 2009
Received: September 14, 2009

Dear Mr. Klaczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.3 Indications For Use – Gamma-bsm

510(k) Number (if known): K091607

Device Name: Gamma-bsm Moldable Bone Substitute Material

Indications for Use:

Gamma-bsm Moldable Bone Substitute Material is an implantable bone graft that is a synthetic calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (i.e. the extremities, posterolateral spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Gamma-bsm Moldable Bone Substitute Material is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091607